



200

350

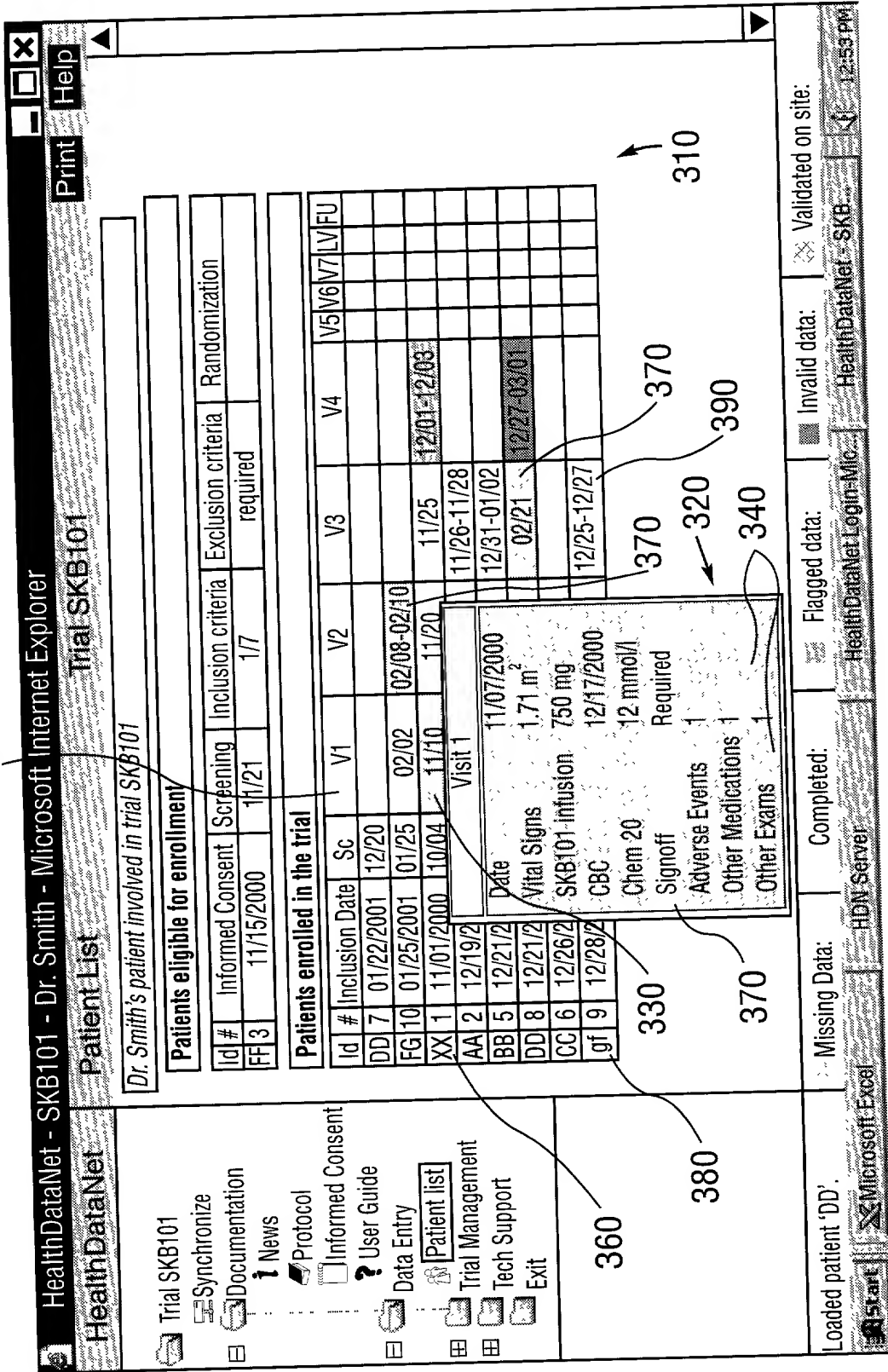


Figure 3

200

420

Patient gf (# 9) Trial SKB101

Initials: gf Number: 9

Random #: 556363 Unit #: 122

Status: Included

Consent: 12/06/2000

Sex: Female

Inclusion: 12/28/2000

Age: 45

End:

430

440

450

410

Back to list

Print

Help

	Screening	Visit1	Visit2	Visit3	Visit4	Visit5	Visit6	Visit7	Last Visit
Date	12/05/2000	12/12/2000	12/19/2000	12/25-12/27	+ [6-8]	+ [6-8]	+ [6-8]	+ [6-8]	+ [6-8]
Inclusion criteria	OK								
Exclusion criteria	OK								
Randomization	#556363								
Medical History	12/28/2000								
Tumor Assessment	4 cm								
Pregnancy test	Negative								
GOG	1								
Physical Exam	12/28/2000		01/24/2001	Brief	Brief	Brief	Brief	Brief	Brief
Vital Signs / BSA	1.74 m <sup>2</sup>	1.66 m <sup>2</sup>	before	before	before	before	before	before	before
CA-125	65 U/ml								
SKB101 infusion	700 mg	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>
CBC	01/25/2001	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion
Chem 20	140 mmol/l	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion	after infusion
Toxicity Assessment									
Signoff	required	required	required	required	required	required	required	required	required
Adverse events		to check	to check	to check	to check	to check	to check	to check	to check
Other Medications	1	1	1	1	1	1	1	1	1
Other Exams	to check	to check	to check	to check	to check	to check	to check	to check	to check

Figure 4

560

**Patient gf (# 9)** **Trial SKB101** **Print** **Help** **Back to list**

Initials: gf      Status: Included      Sex: Female      Age: 45  
 Random #: 556363      Consent: 12/06/2000      Inclusion: 12/28/2000      End:

Number: 9      Unit #: 122

	Screening	Visit1	Visit2	Visit3	Visit4	Visit5	Visit6	Visit7	Last Visit
Date	12/05/2000	12/12/2000	12/19/2000	12/25-12/27	after infusion	after infusion	after infusion	after infusion	after infusion
Inclusion criteria	OK								
Exclusion criteria	OK								
Randomization	#556363								
Medical History	12/28/2000								
Tumor Assessment	4 cm								
Pregnancy test	Negative								
GOG	1								
Physical Exam	12/28/2000		01/24/2001	Brief	Brief	Brief	Brief	Brief	Brief
Vital Signs / BSA	1.74 m <sup>2</sup>	1.66 m <sup>2</sup>	before	before	before	before	before	before	before
CA-125				440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>	440 mg/m <sup>2</sup>
SKB101 infusion				after infusion	after infusion	after infusion	after infusion	after infusion	after infusion
CBC	0			after infusion	after infusion	after infusion	after infusion	after infusion	after infusion
Chem 20	1			after infusion	after infusion	after infusion	after infusion	after infusion	after infusion
Toxicity Assessment				required	required	required	required	required	required
Signoff				to check	to check	to check	to check	to check	to check
Adverse events				to check	to check	to check	to check	to check	to check
Other Medications				to check	to check	to check	to check	to check	to check
Other Exams				to check	to check	to check	to check	to check	to check

**Vital Signs**

Date: 12/01/2000

Height: 65 in

Weight: 145 lb

Temperature: 98 F

Temperature site: Oral

Pulse: 65

Pulse type: Regular

Respiration: 13

Stop: 135 mmHg

Dbp: 86 mmHg

Figure 5

Data validation

Trial SKB101

Print

Help

Add Patient

## Validation status of collected forms

Not/ Available Data

620

Confirmed Data

Initials	Patient	Form	Visit
XX	1	Date: 10/04/2000	Screening
AA	2	Date: 11/15/2000	Visit 1
gf	9	SKB101 infusion: 700 mg	Visit 1
DD	8	SKB101 infusion: 800 mg	Visit 1
XX	1	Signoff: 11/09/2000	Screening

Flagged Data

630B

630A

Initials	Patient	Form	Visit
FF	3	CA-125: 14 U/ml	Screening
FF	3	Inclusion criteria: 1/7	Screening
AA	2	SKB101 infusion: 710 mg	Visit 1
XX	1	Vital Signs: 1.71 m <sup>2</sup>	Visit 1
XX	1	Vital Signs: 11/27/2000	Visit 2

Validated Data

630C

630

Initials	Patient	Form	Visit
XX	1	Chem 20: 15mmol/l	Screening
XX	1	Exclusion criteria: ok	Screening
XX	1	GOG: 1	Screening
XX	1	history: 11/20/2000	All Visits
XX	1	history: 11/21/2000	Screening
XX	1	Tumor Assessment: 13 cm	Screening
fg	10	Vital Signs: 1.85 m <sup>2</sup>	Visit 1

Invalid Data

670

630D

Initials	Patient
BB	5
DD	8
DD	8
DD	8
DD	8
FG	10

Forms

650

Date 02/02/2001  
 Height 170 cm  
 Weight 160 lb  
 Temperature 99 F  
 Temperature site Oral  
 Pulse 65  
 Pulse type Regular  
 Respiration 45  
 Stop 135 mmHg  
 Dbp 70 mmHg

Visit
Screening
Visit 3
Visit 1
Screening
Visit 3
Screening

660

640

610

Figure 6

730 740 720 710

**Vital Signs - Microsoft Internet Explorer**

**Vital Signs** Patient #7 Screening Validate Help

Date: 01/22/2001 (mm/dd/yy)

Height: 165 cm

Weight: 60 kg

Temperature: 96 F

Temperature site: oral

Pulse rate: 58

Rhythm: regular

Respiration: 14

BP: SBP: 125 mmHg

BP: DBP: 65 mmHg

OK Cancel

	Visit5	Visit6	Visit7	Last Visit
CBC	+ [6-8]	+ [6-8]	+ [6-8]	+ [6-8]
Chem 20				
Toxicity Assessment				
Signoff				
Adverse events				
Other Medications				
Other Exams				

Sex: Female  
Inclusion: 12/28/2000  
Age: 45  
End:

750 760A 760B

**Figure 7**

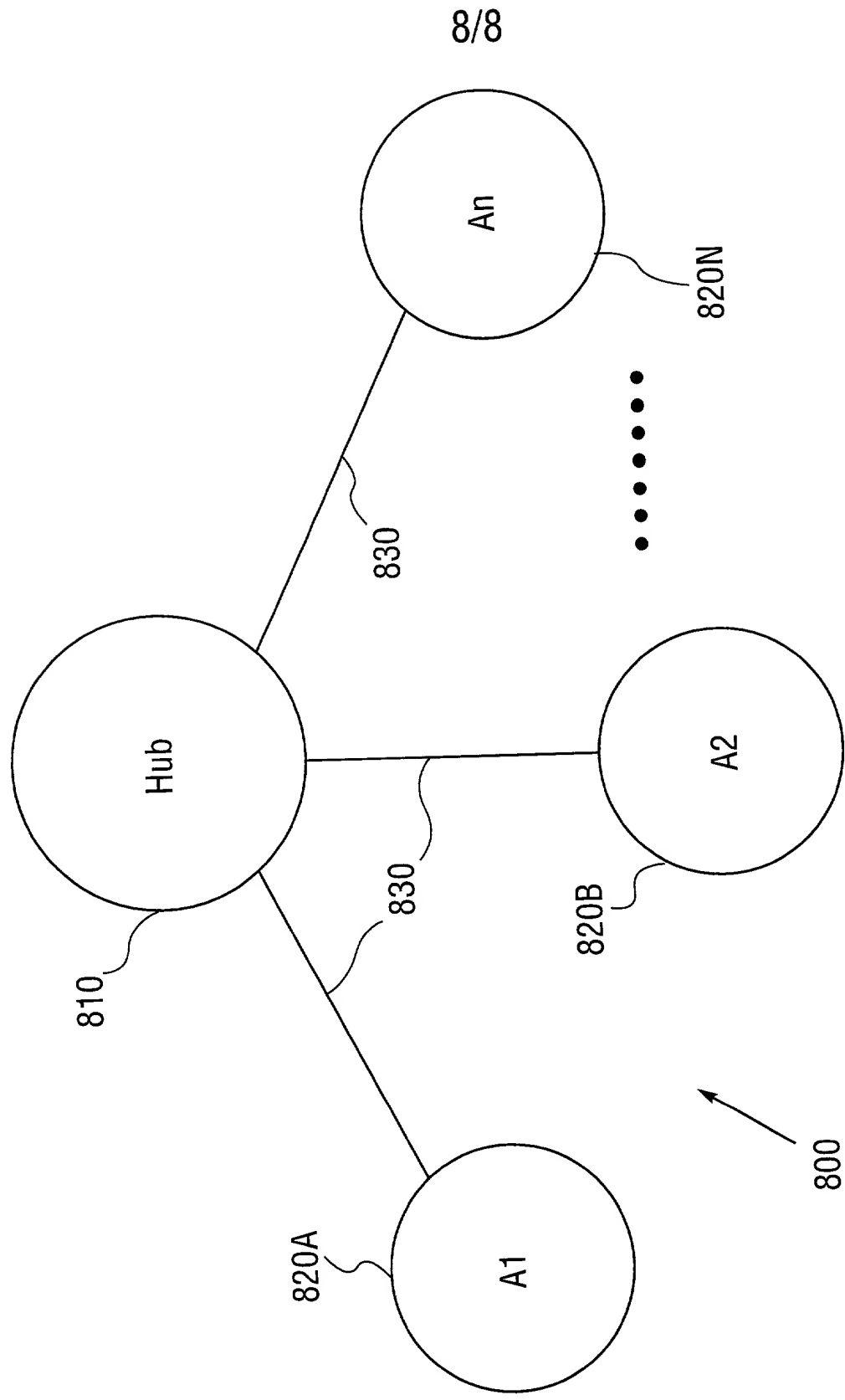


Figure 8